

JAMES S. RICHTER
Of Counsel
(201) 874-7325 (m)
jrichter@midlige-richter.com

May 2, 2025

BY ECF

Honorable José R. Almonte, U.S.M.J.
United States District Court
District of New Jersey
Frank Lautenberg Post Office & U.S. Courthouse
2 Federal Square
Newark, New Jersey 07102

**Re: *Catalyst Pharmaceuticals, Inc. And SERB SA v. Lupin LTD., et al.,*
Civil Action No. 2:23-cv-01197-MEF-JRA; and
Catalyst Pharmaceuticals, Inc. and SERB SA v. Annora Pharma
Private Limited, et al., Civil Action No. 2:23-cv-01194-MEF-JRA**

Dear Judge Almonte:

This firm, together with Buchanan Ingersoll & Rooney PC, represents Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. Please accept this letter on behalf of the Lupin Defendants in Civil Action No. 23-1197 and the Annora/Hetero Defendants in Civil Action No. 23-1194 regarding a scheduling dispute over the length of the deposition of Plaintiffs' expert, Jeffrey David Winkler, Ph.D. The parties met and conferred on April 23, 2025, and were not able to resolve this issue.

I. Defendants' Position

The Lupin action (Civil Action No. 2:23-cv-01197) and Annora action (Civil Action No. 2:23-cv-01194) are not consolidated cases. In these actions, Plaintiffs made a tactical decision to rely on a single expert (Dr. Winkler) to opine on infringement and validity of the asserted '088 patent in both matters, yet have only agreed to produce Dr. Winkler for one day of deposition collectively for both matters. Dr. Winkler issued five expert reports on multiple distinct issues:

Lupin Action (Infringement Reports)

- Opening Expert Report of Jeffrey David Winkler, Ph.D., on Infringement of the '088 patent
- Reply Expert Report of Jeffrey David Winkler, Ph.D., on Infringement of the '088 patent (in response to Lupin's noninfringement expert Dr. W. Dichtel)



T. 908.626.0622
F. 908.626.0322



www.midlige-richter.com
info@midlige-richter.com



645 Martinsville Road
Basking Ridge, NJ 07920

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Annora Action (Infringement Reports)

- Opening Expert Report of Jeffrey David Winkler, Ph.D., on Infringement of the '088 patent
- Reply Expert Report of Jeffrey David Winkler, Ph.D., on Infringement of the '088 patent (in response to Annora's noninfringement expert Dr. D. Norwood)

Lupin and Annora Actions (Validity Report)

- Rebuttal Expert Report of Jeffrey David Winkler, Ph.D., on Definiteness and Validity (in response to all of Defendants' joint invalidity experts and declarant, Dr. R. Perni, Dr. S. Lepore, and M. Dothage)

Plaintiffs should be required to present Dr. Winkler for two deposition days to ensure Defendants have a full and fair opportunity to depose Dr. Winkler. *See* Ex. 1, *United States of America et al., v. Pharmerica Corp. et al.*, No. 11-1326-ESK-AMD, D.I. 615 at 22 (D.N.J. Feb. 17, 2022) (explaining that “it’s not unusual for experts in cases where there are significant reports to be deposed for more than seven hours” and ordering 10 hours total for deposition if the expert is not evasive); Ex. 2, *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, No. 18-1043-LPS/KAJ, D.I. 215, 216 at ¶ 10(g)(3) (D. Del. Oct. 25, 2018) (ordering fourteen hours of deposition times for experts opining on both infringement and validity); Ex. 3, *The Gillette Co. LLC v. Dollar Shave Club, Inc.*, No. 15-1158-LPS-CJB, D.I. 648 (D. Del. Jan. 3, 2019) (ordering two expert depositions to be conducted over more than seven hours because “[w]hen an expert opines on infringement and invalidity the party retaining that expert should expect that a deposition of seven (7) hours may be insufficient”).

Through the meet and confer process, Plaintiffs offered to present Dr. Winkler for one additional hour of deposition (for a total of 8 hours) *See* Ex. 4 (Apr. 15, 2025 Email from D. Guinn). During the telephonic meet and confer dated April 23, 2025, Plaintiffs' counsel made it clear that they would not offer any compromise other than limit the deposition to 8 hours. This offer, however, undermines and fails to acknowledge the complexity and scope of Dr. Winkler's infringement and validity reports. For his infringement opinions, Dr. Winkler submitted two reports (an opening and a reply) to each defendant, which rely on Defendants' respective confidential documents and testing of confidential samples. Lupin and Annora each need time to examine Dr. Winkler on these defendant-specific issues. Moreover, Dr. Winkler's rebuttal validity report alone responds to three separate reports/declarations from Defendants on distinct issues: Dr. Perni's Opening Expert Report on anticipation, obviousness, lack of written description, and lack of enablement; Ms. Dothage's Declaration on reproducing prior art; and Dr. Lepore's Opening Expert Report on indefiniteness.

The inequity in Plaintiffs' proposal is even more apparent in view of the fact that Plaintiffs deposed Dr. Lepore for approximately 4 hours on the single issue of indefiniteness on April 10,



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2025, whereas, Dr. Winkler will be deposed on his five reports issued on (1) infringement with respect to Lupin, (2) infringement in response to Dr. Dichtel, (3) infringement with respect to Annora, (3) infringement in response to Dr. Norwood, and validity based on (4) anticipation, (5) obviousness, (6) prior art reproduction, (7) written description, (8) enablement, and (9) definiteness. Defendants should not be prejudiced or otherwise limited in their ability to depose Dr. Winkler on all the issues he addressed in his expert reports as a result of Plaintiffs' decision to use a single expert to opine on so many distinct issues.

Plaintiffs' argument regarding Dr. Winkler's February 8, 2024's deposition is a red herring. That deposition took place as part of the Markman proceedings, before expert discovery commenced. Moreover, Plaintiffs too took a deposition of Defendants' joint expert, Dr. Lepore, during the Markman proceedings who they again deposed for a second time in response to the opinions he offered during expert discovery.

In a footnote Plaintiffs raise that the Hetero Defendants initially accepted Dr. Winkler's deposition date without exception. What Plaintiffs fail to note is that Plaintiffs emailed each defendant *separately* regarding the deposition of Dr. Winkler (as well as the deposition of Dr. Blair), further supporting Defendants' position that there are defendant-specific issues that Dr. Winkler opined on requiring more than a single day of deposition for both defendants.

It is clear that Defendants Lupin and Annora are coordinating on the depositions. Defendants agreed to jointly depose Plaintiffs' second infringement expert, Dr. Blair, on May 16, even though Dr. Blair issued two reports on each of the defendants. Because the Defendants have separate non-infringement experts, Plaintiffs are able to depose each of those experts separately, for a total of 14 hours as well as Defendants' three invalidity experts/declarant for a total of 21 hours, yet because Plaintiffs used a single expert to respond both those five experts/declarant they think offering Dr. Winkler for an 8-hour deposition is "a compromise".

Defendants respectfully request the Court order Plaintiffs to present Dr. Winkler for deposition for two seven-hour days to provide Defendants sufficient time to examine him on his opinions on infringement and validity.

II. Plaintiffs' Position

Defendants have not and cannot show good cause for departing from the Federal Rules and requiring Dr. Winkler to sit for a two-day, 14-hour deposition. Fed. R. Civ. P. 30(d)(1); *id.*, Advisory Committee Notes to 2000 Amendment, Subdivision (d) (explaining that a party seeking more than a one-day, seven-hour deposition is expected to show good cause). Indeed, Defendants' request is unreasonable and unjustified for several reasons.

First, Defendants made no effort to confer in good faith on the amount of time they believed they actually needed to depose Dr. Winkler. When Defendants first raised an issue with the amount of time for Dr. Winkler's deposition, they asked that he be made available for a second



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day “in the event the deposition cannot be finished in one day.” Ex. 4 (Apr. 9, 2025 Email from Z. Li).¹ In an effort to compromise, Plaintiffs offered to extend the deposition to a total of eight hours. Defendants did not accept Plaintiffs’ offer, nor did they ever indicate exactly how much time they believed they needed or why eight hours (or seven hours for that matter) would be insufficient. During the parties’ subsequent telephonic meet-and-confer, Defendants still provided no justification for an extended deposition beyond the fact that Dr. Winkler served multiple reports and that both Defendants wanted to examine him. Nor did Defendants explain why they would or would not coordinate their examination of Dr. Winkler on the numerous issues that are common to both Defendants. Nor did Defendants provide even an estimate of how much time they believed they needed. Instead, Plaintiffs first learned of Defendants’ purported need for a two-day, 14-hour deposition when Defendants provided a draft of this joint dispute letter. Defendants can hardly proffer that they made a good faith effort to resolve this dispute when they refused to provide an estimate of how much time they believed they actually needed during the conferral process.

Second, Defendants’ demand for a two-day, 14-hour deposition is excessive and unwarranted. As a preliminary matter, Defendants make no mention of the fact that they already deposed Dr. Winkler for over four hours on February 8, 2024, on issues related to their indefiniteness invalidity defense. In view of the four hours Defendants have already spent deposing Dr. Winkler, Plaintiffs’ compromise offer of an eight-hour additional deposition is more than reasonable.

Defendants also fail to acknowledge that all of Dr. Winkler’s opinions concern a single asserted claim from a single patent. Submission of multiple reports is hardly unusual in a patent case. The reason Dr. Winkler submitted multiple reports in this case is that Defendants collectively used five different experts to offer various opinions on a single claim of one patent. For example, Dr. Winkler submitted one rebuttal report on validity and four reports on infringement (two opening and two reply). Dr. Winkler had to submit four infringement reports because Defendants elected to use separate infringement experts. And yet each of Dr. Winkler’s infringement reports pertain to the same issue of infringement of the same asserted claim. Apart from Hetero and Lupin being different companies, there is extensive overlap in Dr. Winkler’s opinions concerning infringement of each product. Thus, the fact that Dr. Winkler served multiple reports in and of itself does not justify a two-day, 14-hour deposition.

Defendants also argue that a two-day, 14-hour deposition is required because the Lupin and Hetero matters are not formally consolidated actions; this argument is disingenuous at best. Defendants have mounted a coordinated attack on the ’088 patent throughout these cases, including sharing multiple experts on the ’088 patent when it suited them. Having elected to mount

¹ Notably, the Hetero Defendants initially accepted Dr. Winkler’s deposition date without exception, *see* Ex. 5 (Apr. 3, 2025 Email from K. Schaubert), before apparently deciding they needed more time and joining the Lupin Defendants in raising an issue over the deposition length, *see* Ex. 4 (Apr. 9, 2025 Email from Z. Li).



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this coordinated attack on the '088 patent when convenient for them, Defendants should not be heard to complain when they are required to likewise coordinate their deposition of Dr. Winkler.

Third, Defendants' request for a two-day, 14-hour deposition is inequitable. Defendants argue that Plaintiffs made a "tactical decision" to rely on Dr. Winkler for infringement and validity of the '088 patent. And yet Defendants' say nothing of their own choice to bury Plaintiffs in eight expert reports from five different experts all for *one* claim of *one* patent. These reports are listed below:

No.	Defendant(s)	Report	Pages*
1	Joint	Opening Expert Report of Robert B. Perni, Ph.D.	66
2	Joint	Opening Expert Report of Salvatore D. Lepore, Ph.D., Regarding Invalidity of U.S. Patent No. 10,626,088	55
3	Joint	Declaration of Mary M. Dothage	15
4	Lupin	Rebuttal Expert Report of William Dichtel, Ph.D., Regarding Noninfringement of U.S. Patent No. 10,626,088	29
5	Hetero	Rebuttal Expert Report of Daniel L. Norwood, Ph.D.	26
6	Joint	Reply Expert Report of Robert B. Perni, Ph.D.	21
7	Joint	Reply Expert Report of Salvatore D. Lepore, Ph.D.	17
8	Joint	Reply Declaration of Mary M. Dothage	8

*Excluding any exhibits, appendices, and/or attachments.

Defendants have not offered to make any of their experts available for 14-hour depositions. And their strategic decision to overload Plaintiffs with eight expert reports from five different experts does not justify subjecting Dr. Winkler to 14 hours of on-the-record deposition testimony for a *single* claim. Their decision to stack experts on one asserted claim in this manner does not warrant dragging Plaintiffs' expert into an excessively lengthy deposition.

Fourth, the case law cited by Defendants undermines their demand for a 14-hour deposition. For example, in *U.S. v. PharMerica Corp., et al.*, the defendant sought a 14-hour deposition of a damages expert but the court called that request "extreme." No. 11-1326-NLH-AMD, D.I. 615, Mot. Hr'g Tr. at 21:22–23 (D.N.J. Feb. 16, 2022). Instead, the court ordered "an additional three hours, for a total of ten hours . . . over the course of two days." No. 11-1326-NLH-AMD, D.I. 613, Order at 1–2 (D.N.J. Feb. 16, 2022). Defendants also cite to a scheduling order in *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, No. 18-1043-KAJ, D.I. 216, Scheduling Order ¶ 10(g)(3) (D. Del. Oct. 25, 2018) ("Each deposition of an expert witness shall be limited to a maximum of seven (7) hours, except that if an expert is testifying on both validity and infringement, then the expert may be deposed for up to an additional seven (7) hours."). However, that same scheduling order consolidated four separate matters into one, *id.* at 1–2, and the proceeding eventually involved more than 40 different defendants. Defendants also rely on *The Gillette Co. LLC v. Dollar Shave Club, Inc., et al.*, No. 15-1158-LPS-CJB, D.I. 648 (D. Del. Jan. 3, 2019). But they fail to acknowledge the relevant facts in that case. The Delaware court allowed



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no more than 11 hours for the expert deposition in question, *id.*, not the 14 hours Defendants imply. Moreover, the expert's opinions pertained to seven different claims and related to infringement, invalidity, and damages. *Gillette*, C.A. No. 1-15-cv-1158-LPS-CJB, D.I. 646, Joint Letter at 2 (Jan. 2, 2019). But here, Defendants already took a four-hour deposition of Dr. Winkler on part of the invalidity issues in Dr. Winkler's reports. A seven-hour deposition would allow them a total of 11 hours of deposition time. Their request for 14 additional hours would result in Dr. Winkler being deposed for a total of 18 hours on issues relating to a single patent claim.

Defendants' have not shown good cause for departing from the Federal Rules and requiring Dr. Winkler to be deposed for 14 hours over two days. Accordingly, the Court should deny Defendants' request. Should the Court agree that some additional time is required notwithstanding Defendants' deficient request, Plaintiffs respectfully request that the deposition be limited to a single day of not more than eight hours.

We thank Your Honor for your consideration of this request. Should Your Honor have any questions, we are available at your convenience.

Respectfully submitted,

s/ James S. Richter

James S. Richter

Encl.

Cc: All Counsel (by ECF and email)



Exhibit 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,)	11-CV-1326 (NLH/AMD)
et al.,)	
)	
Plaintiffs,)	
)	
vs.)	
)	
PHARMERICA CORPORATION,)	
et al.,)	Camden, NJ
)	February 16, 2022
Defendants.)	12:10 p.m.

TRANSCRIPT OF MOTION HEARING
BEFORE THE HONORABLE ANN MARIE DONIO
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

For the Relators:

MICHAEL T. FANTINI, ESQUIRE
SHERRIE R. SAVETT, ESQUIRE
BERGER MONTAGUE PC
1818 Market Street
Suite 3600
Philadelphia, PA 19103

LISA J. RODRIGUEZ, ESQUIRE
SCHNADER, HARRISON, SEGAL &
LEWIS, LLP
Woodland Falls Corporate Park
220 Lake Drive East
Suite 200
Cherry Hill, NJ 08002

For PharMerica:

MICHAEL R. MANTHEI, ESQUIRE
ADRIAN F. SNEAD, ESQUIRE
ANNA KOZLOWSKI, ESQUIRE
HOLLAND & KNIGHT LLP
10 St. James Avenue
11th Floor
Boston, MA 02116

JUDITH H. GERMANO, ESQUIRE
GWEN M. SCHOENFELD, ESQUIRE
GERMANO LAW LLC
460 Bloomfield Avenue
Suite 200
Montclair, NJ 07042

APPEARANCES: (cont.)

For PharMerica:

PETER KOCORAS, ESQUIRE
THOMPSON HINE
20 North Clark Street
Suite 3200
Chicago, IL 60602

Audio Operator:

SUSAN BUSH

Transcribed by:

DIANA DOMAN TRANSCRIBING, LLC
P.O. Box 129
Gibbsboro, NJ 08026
Office: (856) 435-7172
Fax: (856) 435-7124
Email: dianadoman@comcast.net

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Mr. Fantini 25

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Colloquy

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1 (The following was heard via telephone conference
2 at 12:10 p.m.)

3 THE COURT: Good morning -- or I should say good
4 afternoon, everyone. This is Judge Donio. We're on the
5 record in Case No. 11-1326.

6 This is a telephone conference call to address the
7 most recent motion filed by defense counsel to extend certain
8 time periods set forth in the Court's scheduling order, prior
9 scheduling order.

10 May I have the appearances for the record beginning
11 with plaintiff's counsel.

12 MR. FANTINI: It's Michael Fantini from Berger
13 Montague on behalf of relator.

14 MS. SAVETT: Sherrie Savett from Berger & Montague
15 on behalf of relator.

16 MS. RODRIGUEZ: Lisa Rodriguez from Schnader
17 Harrison on behalf of the relator.

18 MR. MANTHEI: Good afternoon, Your Honor. This is
19 Michael Manthei of Holland & Knight on behalf of the defendant
20 PharMerica.

21 MS. GERMANO: Good afternoon, Your Honor. Judy
22 Germano and Gwen Schoenfeld of Germano Law also on behalf of
23 PharMerica.

24 MR. SNEAD: Good afternoon, Your Honor. Adrian
25 Snead of Holland & Knight on behalf of PharMerica.

Colloquy

5

1 MS. KOZLOWSKI: Good afternoon. This is Anna
2 Kozlowski from Holland & Knight also on behalf of PharMerica.

3 MR. KOCORAS: Good afternoon. Peter Kocoras of
4 Thompson Hine on behalf of defendant PharMerica.

5 THE COURT: Is that everyone?

6 MR. FANTINI: Yes, Your Honor.

7 THE COURT: All right. Presently before the Court
8 is an application by way of motion from the defendants to
9 amend the scheduling order dated November 9th, 2021. The
10 motion is document -- let me get the docket number -- number
11 6 --

12 UNIDENTIFIED SPEAKER: 607.

13 THE COURT: 607. 607, is that the motion number?
14 Let me just put it on the record. I have the docket right in
15 front of me. 607.

16 It's been opposed by the plaintiff's counsel and
17 there's been a reply brief filed also by defense in support of
18 the request. And there's a number of requested elements of
19 relief in the motion, and I wanted to address it on a quick
20 turnaround in light of the fact that it impacts certain
21 upcoming deadlines.

22 Are the parties prepared to argue the application or
23 motion today?

24 MR. MANTHEI: This is Michael Manthei. Yes, Your
25 Honor.

1 MR. FANTINI: Yes, Your Honor. It's Michael Fantini
2 for relator.

3 THE COURT: All right. Thank you. Well, this is
4 defense's motion. Let me just start with the first request.
5 That is the request to extend the time for certain expert
6 depositions. And let me note that I've reviewed the
7 submissions. Some of the expert depositions have been
8 scheduled and the current deadline for completion of those
9 depositions I believe is March, and defendants are requesting
10 some additional time, correct?

11 MR. MANTHEI: Yes, Your Honor. This is Michael
12 Manthei on behalf of PharMerica. The current expert
13 deposition deadline is March 31st and we are asking for an
14 additional four weeks until April 29th to complete all six
15 expert depositions.

16 You are correct, Your Honor, that two depositions
17 are scheduled for next week back to back on the 24th and 25th.
18 We anticipate scheduling an additional two depositions in the
19 month of March, and we are requesting that the period be
20 extended to April 29th so that we can adequately prepare for
21 the deposition of relator's primary expert witness, Professor
22 Shakette (phonetic), whose expert reports span 2,000 written
23 pages and includes some 4500 data files that our experts are
24 -- are working on and have been working on for -- for quite
25 some time, Your Honor.

1 We don't believe that it's -- that we can reasonably
2 prepare adequately for Dr. Shakette's deposition by March 31st
3 while also preparing for the depositions of all of the other
4 experts. And this is due largely to the time that it takes to
5 evaluate the data files and the exhibits that have been served
6 with Professor Shakette's expert report.

7 Let me stop there, Your Honor, in case you have any
8 questions.

9 THE COURT: I don't have a question other than are
10 all the other depositions going to be completed before March
11 31st? I thought you had indicated two are scheduled for
12 February, two more for March, but exactly how many experts are
13 we talking about?

14 MR. MANTHEI: There are a total of six experts, Your
15 Honor, and what -- what optimally that we would like to do is
16 complete obviously the depositions scheduled for February,
17 then schedule two more experts for March. That would be
18 PharMerica's expert, Eric Hines (phonetic) and the relator's
19 expert, Professor Hoffman. And then we would like to schedule
20 in April the deposition of Professor Shakette, who again is
21 the relator's primary expert, and our rebuttal expert to
22 Professor Shakette, Dr. Bradford.

23 And the reason we would like to put those two in
24 April again is due to the fact that it is taking quite a bit
25 of time to evaluate Dr. Shakette's extensive opinion or

1 opinions. His affirmative opinion span 1500 written pages and
2 his rebuttal opinion is approximately 550 pages. And that is
3 under -- underpinned by over 3500 data files. And as the
4 affidavit accompanying the motion has set forth, our experts
5 have estimated that it will take them approximately eight to
6 ten weeks to ingest, digest, and evaluate the data and
7 opinions accompanying the rebuttal report.

8 And I just want to be clear that it's not just the
9 rebuttal report itself, but what we need to do as is typical
10 in many cases, we need to compare the rebuttal report to the
11 affirmative -- the affirmative opinions and underlying data
12 calculations in order properly to prepare to depose Professor
13 Shakette, but also in order to prepare our rebuttal witness
14 Dr. Bradford to be deposed as well, too. And we don't believe
15 that this is an unreasonable extension. It is only four weeks
16 and we are continuing to pursue all the other depositions in
17 the meantime.

18 THE COURT: All right. Thank you.

19 MR. FANTINI: Your Honor, may I respond?

20 THE COURT: Of course. Please just state your name.

21 MR. FANTINI: Michael Fantini. It's Michael Fantini
22 on behalf of the relator.

23 You know, all of the alterations and extensions that
24 PharMerica seeks are based primarily upon its receipt of the
25 expert rebuttal report of Dr. Shakette, which we served on

1 February 3rd. And I think it's really important that Your
2 Honor understand the nature of these expert opinions on
3 relator's side so that you can consider that when you consider
4 their request. And I'll keep this very brief.

5 Professor Shakette's two expert reports focused
6 primarily upon his analysis of PharMerica's profit margins
7 when providing drugs to nursing homes' Part A patients. So he
8 took certain revenue data and he subtract -- he subtracted
9 certain costs and revenue to determine margins. And that's
10 what's at issue here. Like this is not overly complicated
11 material.

12 With regard to his -- his report, you know,
13 defendant is throwing out these huge numbers of 500 pages and
14 such, but the reality is his affirmative report, which we
15 served back in September, is 76 pages, that's the body of his
16 report, and only 22 pages are devoted to this margin analysis.
17 And his rebuttal report is 92 pages and only about 20 pages
18 are devoted to an alternative margin analysis that he did.

19 The bulk of his rebuttal report, actually the
20 majority of it is devoted to a discussion of the evidence in
21 the record that supports his opinion, all of which PharMerica
22 has been privy to for a very long time.

23 Our other expert, Professor Hoffman, wrote one
24 report which is 24 pages where she simply responds to the
25 opinions of PharMerica's expert Rossiter (phonetic) regarding

1 the effect of the PPS system on per diem crisis, and whether
2 per diem crisis charged under Part A have an impact on
3 government payment decisions under Part B. That's the gist of
4 her report. It's very straightforward. It's responsive to
5 the opinions of their expert.

6 And then our third expert is Ken Schafermeyer. He
7 wrote one report, it's 28 pages, and he simply discusses
8 whether PharMerica presented claims to the government for
9 federal reimbursement and whether kickback tainted claims are
10 eligible for that reimbursement.

11 And so again that's the nature of our expert
12 opinions. This is not overly complex material to understand
13 or -- or prepare for. And we think the current schedule
14 provides ample time for the parties to meet these deadlines.

15 As Your Honor noted, we have two experts scheduled
16 for next week in February, one from each side. So that -- all
17 that means is PharMerica simply has to take two depositions in
18 the month of March, Professor Shakette and Professor Hoffman.
19 That's it. And then it has to defend two expert depositions.

20 I mean given that they have six lawyers on this
21 phone call, they have the manpower and the resources to take
22 two expert depositions by March 31st, given that it's only
23 mid-February.

24 We proposed that their two experts be deposed in
25 mid-March, which is six months after they received our

1 affirmative reports and three and a half months after they
2 completed their reports. They clearly have adequate time to
3 prepare for those depositions.

4 And then we proposed that Professor Shakette be
5 taken at the very end of March, March 30th, which gives
6 PharMerica two months from the time it received its -- his
7 rebuttal report on February 3rd to prepare for his deposition.
8 I mean PharMerica clearly has the ability and resources to
9 depose Professor Shakette and Professor Hoffman in the month
10 of March.

11 And I just want to give one point of comparison.
12 You know, we did our rebuttal reports on February 3rd, which
13 was only two months including the Christmas holidays after
14 getting Dr. Bradford's report and PharMerica's other expert
15 reports, and it was only a month and a half after we got all
16 of Dr. Bradford's underlying code and information that we
17 needed. So we did that in under two months. And PharMerica
18 can certainly depose Professor Shakette within two months
19 after getting his rebuttal report.

20 I mean they should be operating under the same time
21 frame that we're required to operate on. And -- and so that's
22 our position on the expert depositions, that -- that they --
23 they can easily get this done by March 31st.

24 And I want to make one other point about his
25 rebuttal report. First, in his affirmative report he did a

1 margin analysis where he examined the margins of PharMerica on
2 homes' Part A business. And then in his rebuttal report, all
3 he did was respond to and incorporate the criticisms of
4 PharMerica's expert, Dr. Bradford.

5 Dr. Bradford said that Professor Shakette should use
6 some different data point for revenue, so Professor Shakette
7 ran that data point using his same method and same analysis
8 and came up with an alternative margin analysis, which
9 completely supports his original opinions and which shows the
10 damages are still over \$200 million.

11 So that's all we're talking about. He did an
12 alternative analysis incorporating the criticisms of
13 PharMerica's own expert. And all of this is based on
14 PharMerica's own data, which it's been in possession of for --
15 for years.

16 So Your Honor should understand that this is not
17 really complicated and difficult. And again only 22 pages of
18 Professor Skakette's rebuttal report are devoted to this
19 margin analysis.

20 So it's our position that the current case schedule
21 should remain in place and with reasonable diligence the
22 parties can easily meet these deadlines.

23 THE COURT: Thank you. Any response?

24 MR. MANTHEI: Yes, Your Honor. Again, this is
25 Michael Manthei. There's quite a bit to unpack there and I

1 think I need to address several key issues that my colleague
2 raises in opposition to our motion.

3 While only he points to 20 some odd pages of the
4 report itself deal with the margin analysis, there are 450
5 pages of exhibits that underlie that 20 some odd pages of
6 analysis.

7 This is not as simple as Mr. Fantini would make it
8 out to be. It's not as if these numbers appear on a
9 spreadsheet, like an Excel spreadsheet in a column where you
10 just subtract column A from column B and you get column C.

11 The underlying data consists of a database that is
12 comprised of hundreds of tables with millions of data points
13 in these tables. There is underlying that significant
14 computer code that loops the tables together in order to
15 perform certain calculations that PharMerica has used
16 historically for dispensing its products. The data was never
17 intended to be used in the fashion that Professor Shakette
18 used it.

19 Professor Shakette and -- and relator's other
20 experts have been in possession of this data for over two
21 years and have had all of that time to manipulate it, and
22 they've manipulated it beyond our recognition, which is why it
23 has taken our experts over 4,000 hours combined time to
24 evaluate the affirmative report. And I know that sounds like
25 a lot, and it is, and that is because what Professor Shakette

1 did with the data was manipulate it in a variety of different
2 ways in order to come up with his calculations.

3 For instance, as Mr. Fantini posits, the concept of
4 a contribution margin is fairly simple; it is the revenues
5 minus certain expenses. But determining what those expenses
6 are that he subtracts from the revenue and determining what
7 the revenue actually is, is a complex process that requires
8 the manipulation of the data in these hundreds of tables.

9 And in fact in order to determine what expenses to
10 subtract from revenues, Dr. Shakette performs two regression
11 analyses that are highly complex and that our experts have
12 been evaluating for quite some time now and believe are, you
13 know, highly flawed.

14 In addition to that, the data are incomplete in the
15 sense that it does not cover all time frames for all of -- all
16 of the nursing -- 175 nursing homes that are in this case.
17 Dr. Shakette used a process to fill in those blanks. In other
18 words, he made up data in order to complete his calculations
19 and we have to understand what that process is and how it
20 works in order to properly depose him.

21 And he uses some of the same extrapolations and --
22 and (inaudible) technologies or -- or -- or processes in his
23 rebuttal report. For instance, in paragraph 68 of his
24 rebuttal report, he claims to use a statistical extrapolation
25 analysis in order to rebut or -- rebut Dr. Bradford's rebuttal

1 of his original report.

2 So this is -- this is much more complex than my
3 colleague makes it out to be, and that's evidenced by the fact
4 that while the written portion of the reports may have
5 totaled, according to Mr. Fantini's calculations, you know, 70
6 or 80 pages, the exhibits run to 1500 pages and that's just
7 the exhibits. The underlying -- underlying data files, all of
8 which have to be verified, total over 4,000. So it's -- it's
9 much more complex.

10 And the fact that this is PharMerica's data, it
11 started out as PharMerica's data, but as I -- as I mentioned,
12 relators have had two years to manipulate it and what's come
13 back to us is something completely different from what we sent
14 to them. So again I think that is oversimplifying what is
15 going on here.

16 And -- and finally, Your Honor, the -- the relator's
17 theory of the case has depended almost entirely on this margin
18 analysis and they -- they've represented to the Court on
19 numerous occasions that -- so basically they're saying that,
20 you know, the profit margin is determinative of their
21 (inaudible) theory and (inaudible), that Professor Shakette's
22 calculation of margins is somehow the only meaningful or
23 relevant calculation for conducting this analysis.

24 So it is his opinions are at the core of their case
25 and on that basis alone, PharMerica should have adequate time

1 to prepare for and to depose Professor Shakette. And it's not
2 like we're asking for, you know, six months delay in the -- in
3 the schedule. We're asking for four additional weeks to
4 conduct these depositions.

5 Yes, I understand that Professor Shakette prepared
6 his rebuttal report in -- in eight weeks. During that time,
7 there were no depositions to be taken or to be prepared for.
8 He had the luxury of -- of devoting all of his time to that
9 process, and that's fine. We don't have any recrimination
10 about that, but we feel that PharMerica should have sufficient
11 time based on the advice of its experts.

12 We necessarily have to rely on our experts to help
13 us prepare for these depositions and to understand the very
14 sophisticated calculations that Professor Shakette used in his
15 -- in his affirmative and rebuttal reports. And so far I
16 haven't heard any actual evidence from -- from Mr. Fantini to
17 rebut the evidence that we put into the record as to the
18 amount of time it will take our experts to assist us in
19 preparing for these depositions.

20 So with that, Your Honor, I would request that --
21 that Your Honor extend the deposition period for a brief four
22 weeks so that we can adequately prepare both our -- prepare
23 for our deposition of Professor Shakette and -- and of our
24 rebuttal witness, Dr. Bradford.

25 THE COURT: All right. Is there anything further?

1 MR. FANTINI: Your Honor -- yes, Your Honor. I'd
2 like to respond. It's Michael Fantini. I'll try to be brief.

3 I mean first, as I said, in his rebuttal report
4 Professor Shakette did an alternative margin analysis which
5 incorporated the components that Dr. Bradford said he should
6 use. And so -- in addition the codes that Professor Shakette
7 used was the code taken from Dr. Bradford's report. So this
8 is something in PharMerica's possession.

9 And then when they finally made some requests for
10 additional code and information on February 9th and 10th, we
11 provided that information within hours of their request. And
12 the only new code that exists relates to a single footnote in
13 Professor's Shakette's rebuttal report.

14 Also, while PharMerica is saying there's 1500 pages
15 or 500 pages or some big number, those are just calculations
16 of the margins relating to the 175 nursing homes. You're
17 talking about math. I mean there's no reason that
18 PharMerica's counsel would question Professor Shakette about
19 his math, his arithmetic for 175 homes. I mean I would think
20 a proper examination would focus on his methodology and
21 analysis which he used and applied for all the 175 homes at
22 issue.

23 So, you know, they're making this sound much more
24 complicated than it is because they need more time basically
25 to do every task in the case.

1 And I just need to respond, Professor Shakette did
2 not make up data. The data that PharMerica provided us was
3 missing in certain respects, so he performed extrapolations,
4 which is perfectly acceptable. And he fully explained his
5 methodology and analysis and his calculations in the body of
6 his report, which again only 22 pages are devoted to the
7 margin analysis and the bulk of the rebuttal is devoted to
8 discussion of the evidence.

9 So -- and -- and one other point. Our case does not
10 solely depend upon Professor Shakette. No matter how many
11 times PharMerica says that, it's simply not true. We have a
12 mountain of evidence in the form of deposition testimony and
13 documents that prove that PharMerica knowingly engaged in a
14 swapping scheme, including employees from the pricing
15 department that have testified that offering below cost prices
16 was a common occurrence, common knowledge within the company,
17 and a fact of doing business. So we have a wealth of evidence
18 proving our claims.

19 Professor Shakette's margin analysis will bolster
20 our evidence, but it certainly doesn't make up our sole
21 evidence in the case. And summary judgment is not going to
22 focus solely upon the expert reports, it's going to focus on
23 all of the other evidence that we -- we will present to prove
24 our claims.

25 THE COURT: All right. I think you're -- you're

1 moving somewhat into the merits of the case and I --

2 MR. FANTINI: Okay. That's all -- that's all I
3 wanted to say.

4 THE COURT: Are you complete with your argument?

5 MR. FANTINI: On the issue of expert depositions,
6 yes. We think PharMerica can take two expert depositions in
7 the month of March, which would complete all six experts.

8 THE COURT: All right. Is there anything further
9 from either party on that issue?

10 MR. MANTHEI: This is Michael Manthei again, Your
11 Honor. No, I will rest on my arguments and on the papers.

12 THE COURT: Anything further from plaintiff's
13 counsel?

14 MR. FANTINI: No, Your Honor.

15 THE COURT: All right. I have reviewed the
16 submissions and I've considered the arguments of counsel. The
17 matter is governed by good cause. I'll note that the request
18 was made well before the expiration of the prior deadline and
19 consequently the standard for the Court is whether there's
20 good cause to extend the deadline.

21 The request is for an additional month to take
22 depositions of experts. I don't think that an additional
23 month is necessary, but I will grant a limited extension,
24 finding good cause for a two-week extension in light of when
25 the rebuttal report was served and the scope -- or that is the

1 length of the rebuttal report of the expert.

2 Now, the parties make a lot of argument about what's
3 in the reports and how long they are and how important they
4 are. Really for the Court it's the timing matter. If a
5 rebuttal report of significant length, despite the arguments
6 of plaintiff that it's just a second margin analysis, is
7 served on February 3rd, I find good cause to briefly extend
8 the 3/31/22 deadline for expert depositions to April the 15th.
9 That's a two-week extension.

10 I think that's a viable work extension. The parties
11 can figure out what dates. It also gives opportunity to have
12 to deal with any potential cancellations. And the Court
13 concludes that the defendants have met their burden of
14 demonstrating good cause to extend for a very limited time,
15 two weeks, the depositions of the experts.

16 Now, I'll note that plaintiff's counsel points out
17 that there's six lawyers on the phone for defendants and that
18 they could easily take two depositions, but as I indicated, I
19 feel that the defendants have demonstrated good cause for a
20 short extension of that time period.

21 Now, I'm going to move right to the next issue,
22 which is the dispositive motion deadline. I don't need any
23 further argument on the issue because I'm not going to address
24 whether the dispositive motions and Daubert motions should be
25 bifurcated with the Daubert motions deadline being first.

1 I'm going to dismiss that portion of the motion and
2 direct you to file a letter request to the district judge.
3 That's really a matter that the district judge will need to
4 decide on, how he would like to proceed with those motions.

5 What I'm going to do is keep the deadline the same
6 and then defense counsel can submit their letter to Judge
7 Hillman, but I will push it two weeks because I'm pushing the
8 expert depositions two weeks. So the new deadline for
9 dispositive motions and Daubert motions currently scheduled
10 for 5/13/2021 will be pushed to 5/27/21 and -- I'm sorry, '21
11 -- '22. 5/27/22.

12 And I'm dismissing without prejudice the portion of
13 the motion that requests that only the Daubert motions be
14 scheduled first, and without any opinion on whether that's
15 correct or not, directing the parties to submit with letter
16 requests that issue to the district judge. You now have a new
17 deadline to indicate to the district judge, but it is still
18 one deadline and defense counsel can take that up with the
19 district judge.

20 And the last issue is the number of hours for the
21 deposition of the one expert, and plaintiff's oppose defense's
22 request for a full 14 hours. Defense requests 14 hours. That
23 is extreme, in the Court's view. I don't need to hear any
24 additional argument, unless there's something the parties want
25 to bring to the Court's attention that's not already in the

1 briefs on that issue.

2 MR. MANTHEI: Nothing that's not already in the
3 briefs, Your Honor. This is Michael Manthei.

4 MR. FANTINI: It's Michael Fantini. I don't have
5 anything in addition to say that's not in our letters. But
6 all the other experts are being deposed within seven hours.

7 THE COURT: All right. I understand that, but I
8 will note that this expert has extensive submissions, so I'm
9 going to grant a limited time additional. I'll grant an
10 additional three hours, a total of 10 hours. You can break it
11 down in two days.

12 If the expert is evasive, which I don't expect that
13 to be an issue, and the defendants believe at that time that
14 there's been time spent on evasive answering or other reasons
15 that aren't appropriate under the court rules, then after the
16 first deposition plaintiff's -- defense can send me a letter
17 immediately and ask -- or set up a call at that deposition and
18 ask for more time. But I feel that 10 hours is a reasonable
19 time period.

20 I have seen, it's not unusual for experts in cases
21 where there are significant reports to be deposed for more
22 than seven hours. And I have reviewed the submissions and I
23 find that there's good cause for a limited time period
24 extension of 10 hours total.

25 So the motion is granted in part and dismissed in

1 prejudice -- without prejudice in part and denied to the
2 extent there was a request for 14 hours. And we'll do an
3 order that makes it clear.

4 Is there anything further for today?

5 MR. MANTHEI: Your Honor, this is Michael Manthei
6 again. I just want to make sure that I understand your ruling
7 regarding the deadlines for Daubert and dispositive motions.
8 We did request that they be bifurcated and I understand that
9 that's an issue that you want us to address to the district
10 court judge, Judge Hillman, in a letter request.

11 We made an alternative request also for an extension
12 of time for the filing of Daubert and -- and dispositive
13 motions. We -- we strenuously, you know, believe that six
14 weeks is not enough time to file dispositive and Daubert
15 motions in a case of this magnitude.

16 We have 175 nursing homes, each with their own data
17 and own facts unique to them, and the relator and the Court
18 have stated throughout the course of this litigation that
19 relator must prove its case on a nursing home by nursing home
20 basis.

21 We anticipate that the statement of undisputed facts
22 is going to run into the hundreds of pages and that there will
23 be voluminous exhibits, you know, pages and pages of -- of
24 deposition testimony. And we are actually internally and
25 discussing with counsel our -- you know, just the mechanics of

1 this. We're -- we're thinking that we have to allow at least
2 two weeks just to file through the ECF, based upon our
3 experience with the ECF and the -- and the volume of -- of
4 materials that are going to have to be filed.

5 I would respectfully ask the Court to reconsider our
6 request to extend the deadline for dispositive motions. And I
7 guess I'm not sure if what you're saying is that that will be
8 decided by the district court judge or if that is something
9 that you are going to decide.

10 THE COURT: Okay. Let me -- let me address it this
11 way. I'm not deciding that at this point because I don't know
12 what the district judge is going to request as it relates to
13 Daubert versus dispositive. For example, if the district
14 judge agrees with you and says, okay, just file your Daubert,
15 then that's the deadline, unless the district judge agrees
16 that additional time is necessary or asks me to revisit that
17 issue in light of whatever his decision is on the distinction
18 between Daubert and dispositive motions.

19 Second, I assume and I guess maybe I should just
20 confirm that everybody's working on them already because the
21 fact discovery is over and the only difference would be, would
22 be what's in your expert depositions that could potentially
23 impact a dispositive motion. So I can't imagine that the
24 dispositive motions aren't beginning -- the parties aren't
25 beginning the process of preparing them. And if I'm wrong on

1 that, you should let me know.

2 And, third, let me just ask the plaintiff's counsel,
3 are you also contemplating dispositive or Daubert motions?

4 MR. FANTINI: Well, we -- we may file Daubert
5 motions. They have three experts. We're -- we're continuing
6 to analyze that. I would think that we might file Daubert
7 motions. With regard to dispositive motions, I don't think
8 that's our current intention, no.

9 But I wanted just to respond to PharMerica just put
10 in that alternative proposal, that if the Daubert and
11 dispositive is simultaneous, they want till the end of August
12 to file those briefs, which as Your Honor just pointed out
13 with regard to dispositive, that's a year after fact discovery
14 ended, which was this past August, and it's seven months after
15 they have our rebuttal report. So they have all of our expert
16 reports in their hands.

17 And as Your Honor pointed out, it's the same thing
18 I've been telling them all along, they should be preparing
19 their briefs now. They don't need till the end of August to
20 file these briefs. They could have been writing summary
21 judgment -- their summary judgment brief for a very long time
22 now. And so we strongly oppose that request and especially
23 giving Your Honor just extended it to the end of May. We
24 think that's sufficient time.

25 THE COURT: Well, as I indicated, I'm dismissing

1 that portion of the motion without prejudice because I want to
2 see what the district judge decides with respect to the two
3 different aspects of the filings which could impact that. And
4 once that decision is made, if the defendants still believe
5 they need additional time, they would need to indicate to me
6 in their submissions with whatever renewed request why they
7 aren't done yet, you know, why it's going to take more time.

8 I'm not really sure about the two weeks to do ECF
9 uploading. That's a new one for me. I don't -- maybe that
10 happens. I haven't seen that; I haven't heard about that. I
11 have never had that issue. But I'll leave it for another day
12 for now. I wanted to address what I addressed today.

13 MR. FANTINI: Okay. Thank you, Your Honor.

14 THE COURT: So we're clear for defense counsel and I
15 thank you for bringing that up again so it's clear. I am
16 dismissing without prejudice your request to further extend --
17 your alternative request to further extend the dispositive
18 motion deadline until such time as the district judge resolves
19 the question of what motions should be filed in what order.
20 But for now, it's a March -- I mean a May 27th deadline. So
21 you should be working toward that deadline.

22 MR. MANTHEI: Yes, Your Honor.

23 THE COURT: All right. Anything further from any
24 counsel?

25 MR. FANTINI: None for the plaintiff, Your Honor.

1 MR. MANTHEI: Nothing from PharMerica, Your Honor.

2 THE COURT: All right. Counsel, please stay safe.

3 Have a nice day. We are adjourned.

4 (Proceedings concluded at 12:46 p.m.)

5 * * * * *

6 C E R T I F I C A T I O N

7 I, Roxanne Galanti, court approved transcriber,
8 certify that the foregoing is a correct transcript from the
9 official electronic sound recording of the proceedings in the
10 above-entitled matter.

11 /s/Roxanne Galanti

February 17, 2022

12 ROXANNE GALANTI

13 DIANA DOMAN TRANSCRIBING, LLC

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Exhibit 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVARTIS PHARMACEUTICALS
CORPORATION,

PLAINTIFF,

v.

APOTEX INC. AND APOTEX CORP.,

DEFENDANTS.

Civil Action No. 18-cv-01038-LPS

NOVARTIS PHARMACEUTICALS
CORPORATION,

PLAINTIFF,

v.

TEVA PHARMACEUTICALS USA, INC.
AND ACTAVIS ELIZABETH LLC,

DEFENDANTS.

Civil Action No. 18-cv-01039-LPS

NOVARTIS PHARMACEUTICALS
CORPORATION,

PLAINTIFF,

v.

SUN PHARMACEUTICAL INDUSTRIES,
LTD. ET AL.,

DEFENDANTS.

Civil Action No. 18-cv-01040-LPS

NOVARTIS PHARMACEUTICALS
CORPORATION,

PLAINTIFF,

v.

ACCORD HEALTHCARE INC., ET AL.,

DEFENDANTS.

Civil Action No. 18-cv-01043-LPS

PROPOSED SCHEDULING ORDER

Pursuant to the August 10, 2018 Oral Order (C.A. No. 18-cv-01043, D.I. 84), the parties¹ have met and conferred as to the proposed scheduling order. The parties have determined that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration.

IT IS ORDERED on this 25th day of October 2018 that:

The above-captioned matters shall be consolidated² for all pre-trial purposes. This consolidation shall have no impact on any issue of estoppel. The parties are to file all papers on the lead case docket above (C.A. 18-cv-01043-LPS).

1. For purposes of this Scheduling Order, all defendants in the above-captioned cases are referred to collectively as "Defendants."

2. Apotex has moved the Court to stay the proceedings in *Novartis Pharm. Corp. v. Apotex Inc. and Apotex Corp.* (C.A. 18-cv-01038-LPS) pending Federal Circuit review of the Patent Trial and Appeal Board's final written decision in IPR No. 2017-00854 (D.I. 11) ("Apotex Stay Motion"). As such, Apotex's position is that its case should be stayed for all the reasons set forth in the memorandum in support of the Apotex Stay Motion (D.I. 12).

3. Defendants Nostrum Laboratories Inc., Nostrum Pharmaceuticals, LLC, MSN Laboratories Pvt. Ltd, and MSN Pharmaceuticals Inc. (collectively Nostrum/MSN) intend to join Apotex's motion and request the Court to stay the present case with respect to them. As such, a

¹ Defendant Mylan Pharmaceuticals Inc. joins in the proposed Orders to facilitate discussions amongst the parties, without prejudice to the Court's decision on Mylan's pending motion to dismiss for improper venue in *Novartis Pharm. Corp. v. Accord Healthcare Inc.* (C.A. 18-cv-01043-LPS) (D.I. 118-120), or Mylan seeking alternative relief from the Court, if needed, in light of the Court's recent decision in *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, No. 17-374-LPS (D. Del. Oct. 18, 2018) (granting Mylan's motion to dismiss from Delaware for improper venue).

² As set forth below, Apotex Inc. and Apotex Corp. (collectively "Apotex") have moved to stay proceedings of *Novartis Pharm. Corp. v. Apotex Inc. and Apotex Corp.* (C.A. 18-cv-01038-LPS). In the event the Court denies this motion, Apotex is not opposed to the coordination of the above-captioned matters.

LPA
The
Court
will
deal
with
the
stay
motion
in
due
course.

stay would disrupt the scheduling in this case. Nostrum/MSN therefore requests that a joint Scheduling Order in the present case not be entered as to Nostrum/MSN until the Apotex Stay Motion is decided.

4. **Common Discovery.** The parties shall coordinate activities to reduce duplicative and cumulative discovery that is common to all Defendants (“Common Discovery Issues”). Common Discovery Issues include, but are not limited to, claim construction and validity of the patent-in-suit.

5. **Rule 26(a)(l) and Default Standard Para. 3 Initial Disclosures.** The parties will exchange by **September 17, 2018** the information required by Fed. R. Civ. P. 26(a)(l) and Paragraph 3 of the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("Default Standard") identifying custodial search locations for electronic information. The parties agree that materials containing a Defendant's Highly Confidential Information shall be served only on Plaintiff.

6. **Service and Timing.** The parties consent to service by email, in accordance with Rule 5(b)(2)(E) of the Federal Rules of Civil Procedure. The parties agree that service on any party by email shall be made on both local and national counsel of that party.

7. Joinder of Other Parties and Amendment of Pleadings.

(a) All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **December 14, 2018**.

(b) Any motion to amend (including a motion for leave to amend) a pleading shall **NOT** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the proposed amended pleading as well as a “blackline” comparison to the prior pleading.

(c) Within **seven (7)** days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed **five (5)** pages.

(d) Within **three (3)** days thereafter, the moving party may file a reply letter, not to exceed **two (2)** pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to amend.

8. Motions to Strike

(a) Any motion to strike any pleading or other document shall **NOT** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed **three (3)** pages, describing the basis for the requested relief, and shall attach the document to be stricken.

(b) Within **seven (7)** days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed **five (5)** pages.

(c) Within **three (3)** days thereafter, the moving party may file a reply letter, not to exceed **two (2)** pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to strike.

9. Motion(s) for Preliminary Relief

(a) Plaintiff anticipates possible preliminary injunction proceedings in this matter, in view of the August 18, 2019 expiration date on U.S. Pat. No. 5,604,229, which this Court previously upheld as valid (C.A. 14-cv-01487-LPS, D.I. 309). The schedule herein envisions trial by March 2020, seven months after expiration of the '229 patent. Absent agreement from all Defendants to a stipulation and order precluding selling, offering for sale, marketing, or in any way acting on an approval from FDA for generic Gilenya before a full and final resolution of the present action, Plaintiff currently intends to file a preliminary injunction seeking such relief. To ensure that the Court has adequate time to consider and rule on any such motion, the parties shall adhere to the following procedures:

(i) Each Defendant Party shall notify Plaintiff no later than **January 2, 2019** whether or not that Defendant Party will agree to enter a stipulation and proposed order

prohibiting the Defendant Party from selling, offering for sale, marketing, or in any way acting on an approval from FDA for generic Gilenya before the present action is resolved.

(ii) If any Defendant Party has provided notice that it will not agree to such a stipulation and proposed order, then Plaintiff shall serve and file any motion for a preliminary injunction seeking such relief as to that/those Defendant Party(ies) no later than **February 2, 2019**. Plaintiff and all Defendants involved in preliminary injunction proceedings shall promptly confer and submit by January 15, 2019 a proposal for the length of briefing and format of PI hearing (i.e., oral argument or evidentiary hearing) for the Court's consideration. The Court will schedule an oral hearing on any such motion at a date to be determined, to permit full consideration of the motion and a ruling before the August 18, 2019 expiration date of the '229 patent.

(iii) Any Party participating in preliminary injunction proceedings shall be permitted to submit evidence in support or opposition, including but not limited to documentary evidence, expert testimony, and fact witness testimony. Any Party submitting witness testimony shall make such witness(es) available for deposition at least two weeks after serving the witness(es)' testimony, and at least two weeks before the opposing parties' next papers are due. Any witness(es) submitted in support of Plaintiff's reply papers shall be made available for deposition at least a week before the oral argument date set by the Court.

(iv) In the event preliminary injunction proceedings are begun, the Parties reserve the right to seek modification of all dates in the remainder of this schedule, to account for the need to devote resources to the preliminary injunction process. In the event a Party seeks to modify any date in this schedule, that Party shall meet and confer with the other Parties to attempt to reach agreement on any such modification. Any unresolved disputes shall be submitted pursuant to the Court's procedures for resolving discovery disputes.

(v) Any party can move for leave to file a motion for summary judgment.

10. **Discovery.** Unless otherwise ordered by the Court, the limitations on discovery set forth in Local Rule 26.1 shall be strictly observed.

(a) **Order for Discovery of Electronically Stored Information (“ESI Order”).** The parties shall meet and confer regarding a protocol for ESI. If the parties are not able to reach agreement, they shall submit their dispute pursuant to the Court’s procedure for discovery disputes by **October 23, 2018**.

(b) **Discovery Cut Off.** All fact discovery shall be commenced in time to be completed by **June 4, 2019**. Requests for Admission shall not be considered “discovery” for purposes of the discovery cutoff, and shall be permitted at any time.

(c) **Document Production.**

(1) **Patent, File History, and Identification of Accused Products.** On or before **August 31, 2018**, Plaintiff shall produce the patent-in-suit, including its file history, and identify the accused products.

(2) **ANDA and Related Documents.** On or before **September 7, 2018**, Defendants shall produce any ANDAs seeking approval to market a generic version of Gilenya, including any amendments or supplements filed to date.

(3) **Substantial Completion of Document Production.** Discovery of paper and electronically-stored information shall be substantially completed on or before **January 15, 2019**. No deposition shall be scheduled prior to that date.

(d) **Requests for Admission.** A maximum of **fifty (50)** common requests for admission are permitted for Plaintiff directed to all Defendants, and a maximum of **fifty (50)** common requests for admission are permitted for all Defendants directed towards Plaintiff. No more than an additional **fifteen (15)** individual requests for admission are permitted for Plaintiff directed toward each Defendant Party, and no more than an additional **fifteen (15)** individual requests for admission are permitted for each Defendant Party directed towards Plaintiff. Notwithstanding the foregoing, there is no limitation on the number of requests for admission

relating to the authenticity of documents, which shall be served in time to be completed prior to the close of fact discovery.

(e) **Interrogatories.** A maximum of **twenty-five (25)** common interrogatories are permitted for Plaintiff directed to all Defendants, and a maximum of **twenty-five (25)** common interrogatories are permitted for all Defendants directed towards Plaintiff. No more than an additional **ten (10)** individual interrogatories are permitted for Plaintiff directed toward each Defendant Party, and no more than an additional **ten (10)** individual interrogatories are permitted for each Defendant Party directed towards Plaintiff. Contention interrogatories shall be served in time to permit responses on the schedule below in view of the time for responding to interrogatories set forth in Fed. R. Civ. P. 33. The adequacy of the parties' respective contentions shall be judged by the level of detail each party provides; i.e., the more detail a party provides, the more detail a party shall receive.

(1) **Infringement Contentions and Production of NDA and IPR materials.** On **October 31 2018**, Plaintiff shall serve their infringement contentions consistent with the requirements of Paragraph 4.c. of the Court's Default Standard of Discovery, as well as produce the NDA and IPR materials.

(2) **Invalidity Contentions.** On **December 13, 2018**, Defendants shall serve their invalidity contentions consistent with the requirements of Paragraph 4.d. of the Court's Default Standard for Discovery.

(f) **Depositions.**

(1) **Limitation on Hours for Deposition Discovery.** ~~Plaintiff's~~ **proposal:** Defendants may collectively take a maximum of **one-hundred (100)** hours of deposition testimony of up to **fifteen (15)** party and non-party fact witnesses, including no more than ~~ten (10)~~ **twelve (12)** hours for deposition testimony noticed under Fed. R. Civ. P. 30(b)(6). Plaintiff may take a maximum of **twenty five (25)** hours of deposition testimony of up to 5 witnesses from each Defendant Party, including no more than **eight (8)** hours for any deposition noticed under Fed. R. Civ. P. 30(b)(6). Plaintiff may take a maximum of **twenty five (25)** hours of

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deposition testimony from non-party fact witnesses. Unless otherwise agreed to by the parties, the deposition of an individual witness testifying in an individual capacity shall be limited to ~~seven~~ (7) hours. If a translator is required, each 1.5 hours of actual deposition time will count as 1 hour toward the total time permitted. If an individually-noticed deponent is also designated as a Rule 30(b)(6) witness, the Rule 30(b)(6) portion of that testimony shall not count towards the individual deposition time limit to the extent that the deponent has been designated to provide testimony that is unrelated to the deponent's personal knowledge.] ~~[Defendants' proposal: Defendants may collectively take a maximum of one hundred (100) hours of deposition testimony of up to fifteen (15) party and non-party fact witnesses. Plaintiff may take a maximum of twenty five (25) hours of deposition testimony of up to 5 witnesses from each Defendant Party. Plaintiff may take a maximum of twenty five (25) hours of deposition testimony from non-party fact witnesses. Unless otherwise agreed to by the parties, the deposition of an individual witness testifying in an individual capacity shall be limited to seven (7) hours, except for listed inventors of the patent who may be deposed for up to fourteen (14) hours. If a translator is required, each 2 hours of actual deposition time will count as 1 hour toward the total time permitted.]~~

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(2) **Location of Depositions.** Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court or by agreement of the Parties, and the parties intend to meet and confer on the location of each deposition. A defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.

(g) **Expert Discovery.** Expert discovery shall be commenced in time to be completed by **October 31, 2019**.

(1) **Expert Reports.** For the party with the initial burden of proof on an issue addressed in expert testimony (e.g., Plaintiff infringement reports and Defendant

invalidity reports), expert reports under Fed. R. Civ. Pro. 26(a)(2) are due **July 1, 2019**.

Rebuttal expert reports shall be due **August 15, 2019**. Supplemental reports from Defendants limited to secondary considerations of non-obviousness shall be served on or before **September 5, 2019**. No other expert reports, including supplementations under Fed. R. Civ. P. 26(e), will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

(2) **Expert Reports Supplementation.** The parties agree they will permit expert declarations to be filed in connection with the motions briefing (including case dispositive motions). The parties reserve the right to take depositions of such experts outside the formal expert discovery period, including if the expert has been deposed already, on the subject matter of such a declaration, provided that such subject matter is new and was not already addressed in any of the expert's report(s) that already had been served.

(3) **Expert Depositions.** ~~[Plaintiff's Proposal:~~ Each deposition of an expert witness shall be limited to a maximum of **seven (7)** hours, except that if an expert is testifying on both validity and infringement, then the expert may be deposed for up to an additional **seven (7)** hours.] **[Defendants' Proposal:** Each deposition of an expert witness shall be limited to a maximum of **seven (7)** hours, except that if an expert is testifying on both validity and infringement, then the expert may be deposed for an additional amount of time to be decided by agreement of the parties.]

(4) **Objections to Expert Testimony.** To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than **December 2, 2019**, unless otherwise ordered by the Court. Briefing on such motions is subject to the page limits set out in connection with briefing of case dispositive motions.

(h) **Discovery Matters and Disputes Relating to Protective Orders.**

(1) Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

(2) Should counsel find, after good faith efforts—including verbal communication among Delaware and Lead Counsel for all parties to the dispute—that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall submit a joint letter in substantially the following form:

Dear Judge Stark: The parties in the above referenced matter write to request the scheduling of a discovery teleconference.

The following attorneys, including at least one Delaware Counsel and at least one Lead Counsel per party, participated in a verbal meet-and-confer (in person and/or by telephone) on the following date(s):

Delaware Counsel: _____.

Lead Counsel: _____.

The disputes requiring judicial attention are listed below: [provide here a non-argumentative list of disputes requiring judicial attention]

(3) On a date to be set by separate order, generally not less than **forty eight (48)** hours prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed **three (3)** pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than **twenty-four (24)** hours prior to the conference, any party opposing the application for relief may file a letter, not to exceed **three (3)** pages, outlining that party's reasons for its opposition.

(4) Each party shall submit **two (2) courtesy copies** of its discovery letter and any attachments.

(5) Should the Court find further briefing necessary upon conclusion of the telephone conference, the Court will order it. Alternatively, the Court may choose to

resolve the dispute prior to the telephone conference and will, in that event, cancel the conference.

(6) No motions to compel or motions for protective order shall be filed absent approval of the Court. Absent express approval of the Court following a discovery conference, no motions pursuant to Fed. R. Civ. P. 37 shall be filed.

11. **Application to Court for Protective Order.** Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court by October 23, 2018. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 10(i) above.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

12. **Papers Filed Under Seal.** When filing papers under seal, counsel shall deliver to the Clerk an original and **one (1) copy** of the papers. In accordance with section G of the Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within **seven (7) days** of the filing of the sealed document.

Should any party intend to request to seal or redact all or any portion of a transcript of a court proceeding (including a teleconference), such party should expressly note that intent at the

start of the court proceeding. Should the party subsequently choose to make a request for sealing or redaction, it must, promptly after the completion of the transcript, file with the Court a motion for sealing/redaction, and include as attachments (1) a copy of the complete transcript highlighted so the Court can easily identify and read the text proposed to be sealed/redacted, and (2) a copy of the proposed redacted/sealed transcript. With their request, the party seeking redactions must demonstrate why there is good cause for the redactions and why disclosure of the redacted material would work a clearly defined and serious injury to the party seeking redaction.

13. **Courtesy Copies.** Other than with respect to “discovery matters,” which are governed by paragraph 10(i), and the final pretrial order, which is governed by paragraph 23, the parties shall provide to the Court **two (2) courtesy copies** of all briefs and **one (1) courtesy copy** of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits, etc.). This provision also applies to papers filed under seal.

14. **ADR Process.** This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

15. **Interim Status Report.** On **January 25, 2019**, counsel shall submit a joint letter to the Court with an interim report on the nature of the matters in issue and the progress of discovery to date. Thereafter, if the Court deems it necessary, it will schedule a status conference.

16. **Tutorial Describing the Technology and Matters in Issue.** Unless otherwise ordered by the Court, the parties shall provide the Court, no later than the date on which their opening claim construction briefs are due, a tutorial on the technology at issue. In that regard, the parties may separately or jointly submit a DVD of not more than **thirty (30) minutes**. The tutorial should focus on the technology at issue and should not be used for argument. The parties may choose to file their tutorial(s) under seal, subject to any protective order in effect. Each party may comment, in writing (in no more than **five (5) pages**) on the opposing party’s tutorial. Any such comment shall be filed no later than the date on which the answering claim

construction briefs are due. As to the format selected, the parties should confirm the Court's technical abilities to access the information contained in the tutorial (currently best are "mpeg" or "quicktime").

17. **Claim Construction Issue Identification.** If the Court does not find that a limited earlier claim construction would be helpful in resolving the case, on **January 22, 2019** the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be submitted to the Court on **January 29, 2019**. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

18. **Claim Construction Briefing.** Opening claim construction briefs are due **February 28, 2019**. Responsive construction briefs are due **April 2, 2019**. Local Rule 7.1.3(a)(4) shall control the page limitations for initial (opening) and responsive (answering) briefs.

19. **Hearing on Claim Construction.** Beginning at **2 p.m. on April 23, 2019**, the Court will hear argument on claim construction. The parties shall notify the Court, by joint letter submission, no later than the date on which their answering claim construction briefs are due: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within **sixty (60)** days of the conclusion of the claim construction hearing. If the Court is

unable to meet this goal, it will advise the parties no later than **sixty (60)** days after the conclusion of the claim construction hearing.

20. **Supplementation.** Absent agreement among the parties, and approval of the Court, no later than **February 21, 2019**, the parties must finally supplement, inter alia, the identification of all accused products and of all invalidity references.

21. **Case Dispositive Motions.** Absent agreement between the parties, the Court will generally not hear case dispositive motions in ANDA cases.

22. **Applications by Motion.** Except as otherwise provided herein, any application to the Court shall be by written motion filed with the clerk. Any non-dispositive motion should contain the statement required by D. Del. LR 7.1.1.

23. **Pretrial Conference.** A pretrial conference will be held on **February 21, 2020 at 4 p.m.** Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order with the information required by the form of Revised Final Pretrial Order - Patent, which can be found on the Court's website (www.ded.uscourts.gov), on or before **January 6, 2020**. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(4) for the preparation of the joint proposed final pretrial order. The parties shall provide the Court **two (2)** courtesy copies of the joint proposed final pretrial order and all attachments.

As noted in the Revised Final Pretrial Order - Patent, the parties shall include in their joint proposed final pretrial order, among other things:

(a) A request for a specific number of *hours* for their trial presentations, as well as a requested number of days, based on the assumption that in a typical bench trial day there will be 6 to 7 hours of trial time;

(b) Their position as to whether the Court should allow objections to efforts to impeach a witness with prior testimony, including objections based on lack of completeness and/or lack of inconsistency;

(c) Their position as to whether the Court should rule at trial on objections to expert testimony as beyond the scope of prior expert disclosures, taking time from the parties' trial presentation to argue and decide such objections, or defer ruling on all such objections unless renewed in writing following trial, subject to the proviso that a party prevailing on such a post-trial objection will be entitled to have all of its costs associated with a new trial paid for by the party that elicited the improper expert testimony at the earlier trial; and

(d) Their position as to how to make motions for judgment as a matter of law, whether it be immediately at the appropriate point during trial or at a subsequent break and whether such motions may be supplemented in writing.

The Court will advise the parties at or before the above-scheduled pretrial conference whether an additional pretrial conference will be necessary. The Federal Rules of Civil Procedure and D. Del. LR 16.3 shall govern the pretrial conference.

24. **Motions *in Limine*.** Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each ***SIDE*** shall be limited to **three (3)** *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of **three (3)** pages of argument and may be opposed by a maximum of **three (3)** pages of argument, and the party making the *in limine* request may add a maximum of **one (1)** additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single **three (3)** page submission (and, if the moving party, a single **one (1)** page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

25. **Trial.** This matter is scheduled for a **four (4) day** bench trial, to be held starting on **March 2-6, 2020 at 8:30 a.m.**, with the subsequent trial days also beginning at 8:30 a.m. The trial day will end no later than 5:00 p.m. each day.

26. **Post-Trial Briefing.** The parties will address the post-trial briefing schedule and page limits in the proposed final pretrial order.

27. The parties reserve the right to revisit the deadlines and limitations set forth herein in the event this case is consolidated with any other matters involving different defendants.

EXHIBIT A

**CASE
DEADLINES**

Patent, File History, Identification of Accused Products	August 31, 2018
ANDA Production	August 31, 2018
Fed. R. Civ. P. 26(a)(1) and Del. Para 3 disclosures	September 17, 2018
Submit ESI and Protective Orders	October 23, 2018
Produce IPR materials	October 17, 2018
Infringement Contentions and Production of NDA	October 31, 2018
Invalidity Contentions and Production of References	December 13, 2018
Substantial Completion of Document Production	January 15, 2019
Joinder of Parties/Amend or Supplement Pleadings	December 14, 2018
Fact Discovery Cut Off	June 4, 2019
Supplementation of Accused Products and Invalidity References	February 21, 2019
Interim Status Report	February 21, 2019
Exchange of Claim Terms Needing Construction	January 22, 2019
Joint CC Chart	January 29, 2019
Opening CC Briefs	February 28, 2019
Responsive CC Briefs	April 2, 2019

Hearing on Claim Construction	April 23, 2019
Opening Expert Reports	July 1, 2019
Rebuttal Expert Reports (Plaintiff addresses secondary considerations of non-obviousness)	August 15, 2019
Supplemental Expert Reports (Defendants' address secondary considerations of non-obviousness)	September 5, 2019
Expert Discovery Completion	October 31, 2019
Daubert Motion Deadline	December 2, 2019
Final Pretrial Order	January 6, 2020
Pretrial Conference	February 21, 2020
Bench Trial (4 days)	March 2-6, 2020

McCARTER & ENGLISH, LLP

/s/

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Benjamin A. Smyth (#5528)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
bsmyth@mccarter.com

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Paul E. Torchia
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, NY 10166
(212) 351-4000
JLove@gibsondunn.com
RTrenchard@gibsondunn.com
PTorchia@gibsondunn.com

Andrew P. Blythe
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071
(213) 229-7000
ABlythe@gibsondunn.com

Attorneys for Novartis Pharmaceuticals Corporation

SHAW KELLER LLP

POTTER ANDERSON & CORROON LLP

/s/

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Stephanie E. Byrne (#4446)
Hercules Plaza
1313 North Market Street, 6th Floor
Wilmington, DE 19801
(302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
sobyne@potteranderson.com

OF COUNSEL:

T.O. Kong
WILSON SONSINI GOODRICH & ROSATI
One Market Street
Spear Tower Suite 3300
San Francisco, CA 94105
Tel: (415) 947-2000

Dennis Gregory
WILSON SONSINI GOODRICH & ROSATI
1301 Avenue of the Americas
40th Floor
New York, NY 10019
Tel: (212) 497-7764

Mary Procaccio-Flowers
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304
Tel: 650-849-3025

Diyang Liu
WILSON SONSINI GOODRICH & ROSATI
900 South Capital of Texas Highway
Las Cimas IV, Fifth Floor
Austin, TX 78746
Tel: 512-338-5403

Attorneys for Apotex Inc., Apotex Corp.

HEYMAN ENERIO GATTUSO & HIRZEL LLP

/s/

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com

OF COUNSEL:

Amanda Hollis
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000
ahollis@kirkland.com

Sarah K. Tsou
Gregory Springsted
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
stsou@kirkland.com
greg.springsted@kirkland.com

*Attorneys for Teva Pharmaceuticals USA,
Inc. and Actavis Elizabeth LLC*

SMITH, KATZENSTEIN & JENKINS LLP

/s/

Neal C. Belgam (No. 2721)
Eve H. Ormerod (No. 5369)
1000 West Street, Suite 1501
Wilmington, DE 19801
(302) 652-8400
nbelgam@skjlaw.com
eormerod@skjlaw.com

OF COUNSEL:

Andrew J. Miller
Ajay Kayal
Louis H. Weinstein

/s/

Dominick T. Gattuso (No. 3630)
300 Delaware Ave., Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

OF COUNSEL:

Charles B. Klein
Jovial Wong
WINSTON & STRAWN LLP
1700 K Street, N.W.
Washington, D.C. 20006
(202) 292-5000
CKlein@winston.com
JWong@winston.com

Zachary L. Sorman
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
(312) 558-5600
zsorman@winston.com

*Attorneys for Sun Pharmaceutical Industries,
Ltd., Sun Pharmaceutical Industries, Inc., and
Sun Pharma Global FZE*

MORRIS JAMES LLP

/s/

Kenneth L. Dorsney (#3726)
500 Delaware Ave., Suite 1500
Wilmington, DE 19801-1494
(302) 888-6800
kdorsney@morrisjames.com

OF COUNSEL:

Timothy H. Kratz
George J. Barry III
KRATZ & BARRY LLP
1050 Crown Pointe Parkway
Suite 500

BUDD LARNER, P.C.
150 John F. Kennedy Parkway
Short Hills, NJ 07078
973-379-4800
amiller@buddlerner.com
akayal@buddlerner.com
lweinstein@buddlerner.com

Atlanta, GA 30338
Tel: (404) 341-6600
tkratz@kratzandbarry.com
gbarry@kratzandbarry.com

*Attorneys for Aurobindo Pharma Limited,
Aurobindo Pharma USA, Inc.*

*Attorneys for Accord Healthcare, Inc., Dr.
Reddy's Laboratories, Inc., Dr. Reddy's
Laboratories, Ltd., Torrent Pharmaceuticals
Ltd., and Torrent Pharma Inc.*

PHILLIPS, GOLDMAN, MCLAUGHLIN &
HALL, P.A.

MORRIS JAMES LLP

/s/

John C. Phillips, Jr. (No. 110)
Megan C. Haney (No. 5016)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhllaw.com
mch@pgmhllaw.com

/s/

Kenneth L. Dorsney (#3726)
500 Delaware Ave., Suite 1500
Wilmington, DE 19801-1494
(302) 888-6800
kdorsney@morrisjames.com

OF COUNSEL:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 W. Monroe St.
Chicago, IL 60661
(312) 902-5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

OF COUNSEL:

Howard S. Suh
HOLLAND & KNIGHT LLP
31 West 52nd Street
New York, New York 10019
(212) 513-3200
howard.suh@hklaw.com

*Attorneys for Bionpharma Inc., Hetero USA Inc.,
Hetero Labs Limited, Hetero Labs Limited Unit-
V, Princeton Pharmaceutical Inc.*

*Attorneys for Biocon Limited, Biocon
Pharma, Inc.*

RICHARDS, LAYTON & FINGER, P.A.

PHILLIPS, GOLDMAN, MCLAUGHLIN &
HALL, P.A.

/s/

Kelly E. Farnan (#4395)
Sara M. Metzler (#6509)
One Rodney Square

/s/

John C. Phillips, Jr. (#110)
Megan C. Haney (#5016)
1200 North Broom Street

920 N. King Street
Wilmington, Delaware 19801
(302) 651-7705
farnan@rlf.com
metzler@rlf.com

*Attorneys for Breckenridge Pharmaceutical,
Inc., Standard Chemical & Pharmaceutical
Co. Ltd.*

Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
mch@pgmhlaw.com

OF COUNSEL:
Elaine Herrmann Blais
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000
eblais@goodwinlaw.com

Michael B. Cottler
Cindy Chang
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800
mcottler@goodwinlaw.com

cindychang@goodwinlaw.com Attorneys for
*Emcure Pharmaceuticals, Ltd., Heritage
Pharmaceuticals Inc.*

STAMOULIS & WEINBLATT, LLP

/s/

Stamatios Stamoulis (#4606)
Richard C. Weinblatt (#5080)
Two Fox Point Centre
6 Denny Road, Suite 307
Wilmington, DE 19809
(302) 999-1540
stamoulis@swdelaw.com
weinblatt@swdelaw.com

OF COUNSEL:
Aaron F. Barkoff
Alejandro Menchaca
MCANDREWS, HELD & MALLOY, LTD.
500 West Madison St., 34th Floor
Chicago, IL 60661
(312) 775-8000

YOUNG CONAWAY STARGATT &
TAYLOR, LLP

/s/

Adam W. Poff (#3990)
Rodney Square
1000 North King Street
Wilmington, Delaware 19801
(302) 571- 6600
apoff@ycst.com

*Attorneys for Glenmark Pharmaceuticals, Inc.,
USA and Glenmark Pharmaceuticals Limited*

abarkoff@mcandrews-ip.com
amenchaca@mcandrews-ip.com

Attorneys for Ezra Ventures LLC

STAMOULIS & WEINBLATT, LLP

/s/

Stamatios Stamoulis (#4606)
Richard C. Weinblatt (#5080)
Two Fox Point Centre
6 Denny Road, Suite 307
Wilmington, DE 19809
(302) 999-1540
stamoulis@swdelaw.com
weinblatt@swdelaw.com

*Attorneys for HEC Pharm Co., HEC Pharm
Group, HEC Pharm USA Inc.*

FINGER & SLANINA, LLC

/s/

David L. Finger (#2556)
One Commerce Center
1201 N Orange Street, 7th Floor
Wilmington, DE 19801-1186
Tel: 302-573-2525

OF COUNSEL:

David Austin
Carolyn Chang
Marton Ribera Schumann & Chang LLP
400 Oyster Point Blvd. Suite 539
South San Francisco, CA 94080
Tel: 415.360.2511
daustin@martonribera.com
carolyn@martonribera.com

*Attorneys for Nostrum Laboratories, Inc.,
Nostrum Pharmaceuticals, LLC, MSN
Laboratories Private Limited, MSN
Pharmaceuticals Inc.*

Carlton R. Asher, Jr.
LAW OFFICES OF CARLTON R. ASHER,
JR.
110 East 59th Street, Suite 2200
New York, NY 10022
(212) 308-7171
asherlaw@att.net

Bridgette Y. Ahn
LAW OFFICES OF BRIDGETTE Y. AHN
200 Park Avenue, Suite #1700
New York, NY 10166
(212) 537-4409
bahn@bahnlaw.com

*Attorneys for Nostrum Laboratories Inc., and
Nostrum Pharmaceuticals, LLC*

RICHARDS, LAYTON & FINGER, P.A.

/s/

Fredrick L. Cottrell, III (#2555)
Jason J. Rawnsley (#5379)
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
(302) 651-7700
cottrell@rlf.com
rawnsley@rlf.com

OF COUNSEL:

Shannon M. Bloodworth
Brandon M. White
PERKINS COIE LLP
700 13th Street NW
Washington, DC 20001
(202) 654-6200
SBloodworth@perkinscoie.com
BMWhite@perkinscoie.com

Bryan D. Beel, Ph.D.
PERKINS COIE LLP
1120 NW Couch Street, 10th Floor
Portland, OR 97209-4128
(503) 727-2116
BBeel@perkinscoie.com

Attorneys for Mylan Pharmaceuticals Inc.

PINCKNEY, WEIDINGER, URBAN &
JOYCE LLC

/s/

Helena C. Rychlicki (DE No. 3996)
Elizabeth Wilburn Joyce (DE No. 3666)
3711 Kennett Pike, Suite 210
Greenville, DE 19807
(302) 504-1497 (telephone)
(302) 655-5123 (facsimile)
hrychlicki@pwujlaw.com
ewilburnjoyce@pwujlaw.com

RICHARDS, LAYTON & FINGER, P.A.

/s/

Steven J. Fineman (#4025)
Tyler E. Cragg (#6398)
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
(302) 651-7700
fineman@rlf.com
cragg@rlf.com

OF COUNSEL:

David H. Silverstein
AXINN, VELTROP & HARKRIDER LLP
114 West 47th Street
22nd Floor
New York, NY 10036
(212) 728-2200
dsilverstein@axinn.com

Aziz Burgy
Ricardo S. Camposanto
AXINN, VELTROP & HARKRIDER LLP
950 F Street, N.W.
Washington, D.C. 20004
(202) 912-4700
aburgy@axinn.com
rcamposanto@axinn.com

Attorneys for Par Pharmaceutical, Inc.

PHILLIPS, GOLDMAN, MCLAUGHLIN &
HALL, P.A.

/s/

John C. Phillips, Jr. (No. 110)
Megan C. Haney (No. 5016)
1200 North Broom Street
Wilmington, Delaware 19806-4204
Phone: (302) 655-4200
jcp@pgmhlaw.com
mch@pgmhlaw.com

*Attorneys for Strides Pharma Global Pte Ltd.
and Strides Pharma Inc.*

OF COUNSEL:
Michael J. Gaertner
David B. Abramowitz
Carolyn A. Blessing
Emily L. Savas
Jonathan B. Turpin
LOCKE LORD LLP
111 South Wacker Drive
Chicago, IL 60606
Telephone: (312) 443-0700
mgaertner@lockelord.com
dabramowitz@lockelord.com
cblessing@lockelord.com
esavas@lockelord.com
jturpin@lockelord.com

*Attorneys for Zydus Pharmaceuticals (USA)
Inc., Cadila Healthcare Limited*

MORRIS JAMES LLP

/s/

Kenneth L. Dorsney (#3726)
500 Delaware Ave., Suite 1500
Wilmington, DE 19801-1494
(302) 888-6800
kdorsney@morrisjames.com

OF COUNSEL:
Stephen R. Auten
Richard T. Ruzich
Roshan P. Shrestha, Ph.D.
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
(312) 527-4000
sauten@taftlaw.com
rruzich@taftlaw.com
rshrestha@taftlaw.com

Attorneys for Alkem Laboratories, Ltd.

Dated: October 23, 2018

SO ORDERED this 25th day of October, 2018.



THE HONORABLE LEONARD P. STARK
CHIEF UNITED STATES DISTRICT JUDGE

Exhibit 3

**U.S. District Court
District of Delaware (Wilmington)
CIVIL DOCKET FOR CASE #: 1:15-cv-01158-LPS**

The Gillette Company LLC v. Dollar Shave Club, Inc.

Assigned to: Judge Leonard P. Stark

Related Cases: [1:18-cv-01306-LPS-CJB](#)

[1:18-cv-00876-LPS](#)

Case in other court: Third Circuit, 17-02741

Cause: 35:271 Patent Infringement

Date Filed: 12/17/2015

Date Terminated: 04/02/2019

Jury Demand: Both

Nature of Suit: 830 Patent

Jurisdiction: Federal Question

Plaintiff

The Gillette Company

TERMINATED: 08/13/2018

represented by **Jack B. Blumenfeld**

Morris, Nichols, Arsht & Tunnell LLP

1201 North Market Street

P.O. Box 1347

Wilmington, DE 19899

(302) 658-9200

Email: Jbbefiling@mnat.com

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Alexandra D. Valenti

Email: avalenti@goodwinlaw.com

PRO HAC VICE

ATTORNEY TO BE NOTICED

Charles T. Cox , Jr.

Email: Charlie.Cox@wilmerhale.com

TERMINATED: 09/19/2018

PRO HAC VICE

Elaine H. Blais

Email: eblais@goodwinlaw.com

PRO HAC VICE

ATTORNEY TO BE NOTICED

Jennifer A. Albert

Email: jalbert@goodwinlaw.com

TERMINATED: 02/28/2019

PRO HAC VICE

Kevin J. DeJong

Email: kdejong@goodwinlaw.com

PRO HAC VICE

ATTORNEY TO BE NOTICED

(See above for address)
TERMINATED: 07/17/2018

Terry L. Wit
(See above for address)
TERMINATED: 07/17/2018

V.

Counter Defendant

The Gillette Company LLC

represented by **Jack B. Blumenfeld**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Rodger Dallery Smith , II
(See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
12/17/2015	<u>1</u>	COMPLAINT FOR PATENT INFRINGEMENT filed with Jury Demand against Dollar Shave Club, Inc. - Magistrate Consent Notice to Pltf. (Filing fee \$ 400, receipt number 0311-1845756.) - filed by The Gillette Company. (Attachments: # <u>1</u> Exhibit A, # <u>2</u> Civil Cover Sheet)(cna) (Entered: 12/17/2015)
12/17/2015	<u>2</u>	Notice, Consent and Referral forms re: U.S. Magistrate Judge jurisdiction. (cna) (Entered: 12/17/2015)
12/17/2015	<u>3</u>	Report to the Commissioner of Patents and Trademarks for Patent/Trademark Number(s) 6,684,513. (cna) (Entered: 12/17/2015)
12/17/2015	<u>4</u>	Disclosure Statement pursuant to Rule 7.1: identifying Corporate Parent Proctor & Gamble Co. for The Gillette Company filed by The Gillette Company. (cna) (Entered: 12/17/2015)
12/17/2015		Summons Issued with Magistrate Consent Notice attached as to Dollar Shave Club, Inc. on 12/17/2015. Requesting party or attorney should pick up issued summons at the Help Desk, Room 4209, or call 302-573-6170 and ask the Clerk to mail the summons to them. (cna) (Entered: 12/17/2015)
12/21/2015	<u>5</u>	SUMMONS Returned Executed by The Gillette Company. Dollar Shave Club, Inc. served on 12/21/2015, answer due 1/11/2016. (Smith, Rodger) (Entered: 12/21/2015)
12/23/2015		Case Assigned to Judge Leonard P. Stark. Please include the initials of the Judge (LPS) after the case number on all documents filed. (rjb) (Entered: 12/23/2015)
01/04/2016	6	ORAL REFERRAL ORDER: This case will be governed by Judge Stark's Revised Procedures for Managing Patent Cases (see www.ded.uscourts.gov). In accordance with the Revised Procedures, IT IS HEREBY ORDERED that: 1. any and all matters relating to scheduling, including entry of a Scheduling Order, are referred to Magistrate Judge Burke; 2. any and all motions to dismiss, stay, and/or transfer venue, relating to all or any part of the case, whenever such motions may be filed, are referred to Judge Burke for disposition or report and recommendation, to the full extent permitted by the Constitution, statute, and rule; and 3. within seven (7) days of the date of this Referral Order, the plaintiff(s) shall file the Procedures Order, which is found on Judge Stark's

		(ntl) (Entered: 01/03/2019)
01/03/2019	648	ORAL ORDER: Having reviewed the parties' letter (D.I. 646), IT IS HEREBY ORDERED that Defendants may depose Dr. Ross (Plaintiff's expert on infringement and on at least "a portion of validity") for no more than eleven (11) hours and Defendants may also depose Dr. Ennis (another Plaintiff expert on validity) for no more than seven (7) hours. Plaintiff's assertions that "Defendants' position is unsupported" and that depositions greater than seven (7) hours are "always... done on an agreed basis before the scheduling conference" are incorrect; their contention that what Defendants propose "is manifestly unfair" is unpersuasive. When an expert opines on infringement and invalidity the party retaining that expert should expect that a deposition of seven (7) hours may be insufficient. Here, the Court finds that eleven (11) hours is a reasonable and appropriate amount of time to depose Dr. Ross and that there is no meritorious basis to subtract deposition time from Plaintiff's other invalidity expert. ORDERED by Judge Leonard P. Stark on 1/3/19. (ntl) (Entered: 01/03/2019)
01/07/2019	649	NOTICE OF SERVICE of Reply Expert Report of Caroline A. Ross, Ph.D. Regarding Infringement filed by The Gillette Company LLC.(Smith, Rodger) (Entered: 01/07/2019)
01/08/2019	650	NOTICE to Take Deposition of Daniel Ennis, Ph.D, DSc on January 16, 2019 filed by Dollar Shave Club, Inc., Dorco Company Ltd., Pace Shave Inc..(Fry, David) (Entered: 01/08/2019)
01/08/2019	651	NOTICE to Take Deposition of Donald J. Bray, Richard A. Haber, Ph.D. and James E. Malackowski on January 11, 2019; January 16, 2019 and January 16, 2019, respectively filed by The Gillette Company LLC.(Flynn, Michael) (Entered: 01/08/2019)
01/09/2019	652	NOTICE to Take Deposition of Caroline A. Ross, Ph.D. on January 11 and January 12, 2019 at 9:00 a.m. filed by Dollar Shave Club, Inc., Dorco Company Ltd., Pace Shave Inc..(Fry, David) (Entered: 01/09/2019)
01/10/2019	653	STIPULATION TO EXTEND TIME for the parties to file case dispositive and Daubert motions to January 22, 2019 - filed by The Gillette Company LLC. (Flynn, Michael) (Entered: 01/10/2019)
01/10/2019	654	NOTICE OF SERVICE of (1) Defendant Dollar Shave Club, Inc.'s Fifth Amended Initial Disclosures Pursuant to Rule 26(a)(1) and Paragraph 3 of the Delaware Default Standard for Discovery (2) Defendant Pace Shave, Inc.'s Third Amended Initial Disclosures Pursuant to Rule 26(a)(1) and Paragraph 3 of the Delaware Default Standard for Discovery (3) Defendant Dorco Company, Ltd.'s Third Supplemental Initial Disclosures Pursuant to Rule 26(a)(1) and Paragraph 3 of the Delaware Default Standard for Discovery filed by Dollar Shave Club, Inc., Dorco Company Ltd., Pace Shave Inc..(Fry, David) (Entered: 01/10/2019)
01/14/2019	655	MOTION for Pro Hac Vice Appearance of Attorney Kevin P. Martin - filed by The Gillette Company LLC. (Smith, Rodger) (Entered: 01/14/2019)
01/15/2019		SO ORDERED, re 653 STIPULATION TO EXTEND TIME for the parties to file case dispositive and Daubert motions to January 22, 2019 filed by The Gillette Company LLC. Signed by Judge Leonard P. Stark on 1/14/19. (ntl) (Entered: 01/15/2019)
01/16/2019		SO ORDERED, re 655 MOTION for Pro Hac Vice Appearance of Attorney Kevin P. Martin filed by The Gillette Company LLC. Signed by Judge Leonard P. Stark on 1/16/19. (ntl) (Entered: 01/16/2019)
01/22/2019	656	MOTION for Summary Judgment of <i>No Infringement</i> - filed by Dollar Shave Club, Inc., Dorco Company Ltd., Pace Shave Inc.. (Attachments: # 1 Text of Proposed Order)(Fry, David) (Entered: 01/22/2019)

Exhibit 4

From: [Davin Guinn](#)
To: [Zhibin Li](#); [Firdapse-Litigation](#); [Chevalier, Charles H.](#); [Gaddis, Christine A.](#); [Caracappa, Michael V.](#)
Cc: [CD-Lupin-Amifampridine](#); [jrichter@midlige-richter.com](#); [Lukas, Aaron](#); [Coblentz, W. Blake](#); [Schaubert, Keri](#); [eabraham@hillwallack.com](#); [kbutler@hillwallack.com](#); [William P. Murtha](#)
Subject: RE: Catalyst v. Lupin - Expert Depositions
Date: Tuesday, April 15, 2025 12:14:03 PM
Attachments: [image001.png](#)
[image002.png](#)



Zhibin,

Thank you for confirming Lupin's acceptance of May 16 for the deposition of Dr. Blair.

Given that Dr. Winkler's expert opinions pertain to only one asserted claim of one asserted patent (the '088 patent), Plaintiffs are not willing to make him available for deposition on two separate days. As a compromise, however, Plaintiffs are amenable to making Dr. Winkler available for an additional hour (8 total hours) on May 22. Please confirm we have an agreement.

Best,
Davin

Davin Guinn

Associate

[Sterne, Kessler, Goldstein & Fox P.L.L.C.](#)

Email: dguinn@sternekessler.com

Direct: 202.772.8530

IP Assistant: Renée Moore

Direct: 202.772.8820 **Main:** 202.371.2600

From: Zhibin Li <zhibin.li@bipc.com>

Sent: Wednesday, April 9, 2025 4:45 PM

To: Davin Guinn <dguinn@sternekessler.com>; Firdapse-Litigation <Firdapse-Litigation@sternekessler.com>; Chevalier, Charles H. <CChevalier@gibbonslaw.com>; Gaddis, Christine A. <cgaddis@gibbonslaw.com>; Caracappa, Michael V. <MCaracappa@gibbonslaw.com>

Cc: CD-Lupin-Amifampridine <Lupin-Amifampridine@bipc.com>; jrichter@midlige-richter.com; Lukas, Aaron <ALukas@cozen.com>; Coblentz, W. Blake <wcoblentz@cozen.com>; Schaubert, Keri <KSchaubert@cozen.com>; eabraham@hillwallack.com; kbutler@hillwallack.com; William P. Murtha <wmurtha@hillwallack.com>

Subject: RE: Catalyst v. Lupin - Expert Depositions

EXTERNAL EMAIL: Use caution before clicking links or attachments.

Counsel,

Lupin accepts May 16 for Dr. Blair's deposition.

Dr. Winkler has submitted five reports (on infringement and validity) in both Lupin and Hetero litigations. Lupin plans to coordinate with Hetero for the Winkler deposition, however, Lupin and Hetero request that Plaintiffs make Dr. Winkler available for deposition on both May 22 and 23, in the event the deposition cannot be finished in one day with two parties needing to examine him. Please let us know if plaintiffs agree to this proposal or let us know your availability for a meet and confer to discuss.

Zhibin

Zhibin Li
Shareholder

640 5th Avenue, 9th Floor
New York, NY 10019-6102
212 440 4407 (o)
860 204 2562 (c)
zhibin.li@bipc.com

Buchanan

[vCard](#) | [Bio](#) | [BIPC.com](#) | [Twitter](#) | [LinkedIn](#)

From: Davin Guinn <dguinn@sternekessler.com>
Sent: Wednesday, April 9, 2025 10:48 AM
To: CD-Lupin-Amifampridine <Lupin-Amifampridine@bipc.com>; jrichter@midlige-richter.com
Cc: Firdapse-Litigation <Firdapse-Litigation@sternekessler.com>; Chevalier, Charles H. <CChevalier@gibbonslaw.com>; Gaddis, Christine A. <cgaddis@gibbonslaw.com>; Caracappa, Michael V. <MCaracappa@gibbonslaw.com>
Subject: RE: Catalyst v. Lupin - Expert Depositions

Counsel,

Please confirm your acceptance of the dates below for the depositions of Drs. Blair and Winkler.

Plaintiffs would like to finalize these dates as soon as possible.

Best,
Davin

Davin Guinn
Associate
Sterne, Kessler, Goldstein & Fox P.L.L.C.
Email: dguinn@sternekessler.com
Direct: 202.772.8530

IP Assistant: Renée Moore
Direct: 202.772.8820 **Main:** 202.371.2600

From: Davin Guinn <dguinn@sternekessler.com>

Sent: Friday, April 4, 2025 11:51 AM

To: CD-Lupin-Amifampridine <Lupin-Amifampridine@bipc.com>; jrichter@midlige-richter.com

Cc: Firdapse-Litigation <Firdapse-Litigation@sternekessler.com>; Chevalier, Charles H. <CChevalier@gibbonslaw.com>; Gaddis, Christine A. <cgaddis@gibbonslaw.com>; Caracappa, Michael V. <MCaracappa@gibbonslaw.com>

Subject: RE: Catalyst v. Lupin - Expert Depositions

Counsel,

Please confirm acceptance of the dates specified below as soon as possible.

For the sake of coordination, we note that counsel for Hetero has already accepted these dates. Dr. Blair and Dr. Winkler will only be made available once.

Thanks,
Davin

Davin Guinn

Associate

Sterne, Kessler, Goldstein & Fox P.L.L.C.

Email: dguinn@sternekessler.com

Direct: 202.772.8530

IP Assistant: Renée Moore

Direct: 202.772.8820 **Main:** 202.371.2600

From: Davin Guinn <dguinn@sternekessler.com>

Sent: Friday, March 28, 2025 5:10 PM

To: CD-Lupin-Amifampridine <Lupin-Amifampridine@bipc.com>; jrichter@midlige-richter.com

Cc: Firdapse-Litigation <Firdapse-Litigation@sternekessler.com>; Chevalier, Charles H. <CChevalier@gibbonslaw.com>; Gaddis, Christine A. <cgaddis@gibbonslaw.com>; Caracappa, Michael V. <MCaracappa@gibbonslaw.com>

Subject: Catalyst v. Lupin - Expert Depositions

Counsel,

Plaintiffs' experts are available for deposition at Sterne Kessler's office (1101 K Street NW, 10th Floor, Washington, D.C. 20005) on the following dates:

- Dr. Blair: Friday, May 16
- Dr. Winkler: Thursday, May 22

Please confirm acceptance of these dates as soon as feasible.

Best,
Davin



Davin Guinn

Associate

Sterne, Kessler, Goldstein & Fox P.L.L.C.

1101 K Street NW, 10th Floor, Washington, DC 20005

Email: dguinn@sternekessler.com

Direct: 202.772.8530

IP Assistant: Renée Moore

Direct: 202.772.8820 **Main:** 202.371.2600

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Exhibit 5

From: Schaubert, Keri <KSchaubert@cozen.com>
Sent: Thursday, April 3, 2025 10:14 AM
To: Davin Guinn; Firdapse-Litigation; Chevalier, Charles H.; Gaddis, Christine A.; Caracappa, Michael V.
Cc: Coblentz, W. Blake; Lukas, Aaron; eabraham@hillwallack.com; wmurtha@hillwallack.com; Kristine L. Butler
Subject: RE: Catalyst v. Hetero - Expert Depositions

EXTERNAL EMAIL: Use caution before clicking links or attachments.

Counsel,

We accept the below dates for the depositions of Drs. Blair, Winkler, Wymer, and McQueen.

In addition, Dr. Lipkin is available for deposition at Cozen O'Connor's New York office on Monday, May 12th. Please let us know as soon as feasible if Plaintiffs can accept that date.

Best,
Keri



Keri L. Schaubert, Ph.D.
Member | Cozen O'Connor
3 WTC, 175 Greenwich Street 55th Floor | New York, NY 10007
P: 212-883-2258 F: 646-461-3331 C: 734-276-4959
[Email](#) | [Bio](#) | [Map](#) | [cozen.com](#)

From: Davin Guinn <dguinn@sternekessler.com>
Sent: Friday, March 28, 2025 5:06 PM
To: Schaubert, Keri <KSchaubert@cozen.com>; Coblentz, W. Blake <WCoblentz@cozen.com>; Lukas, Aaron <ALukas@cozen.com>; eabraham@hillwallack.com; wmurtha@hillwallack.com; Kristine L. Butler <kbutler@hillwallack.com>
Cc: Firdapse-Litigation <Firdapse-Litigation@sternekessler.com>; Chevalier, Charles H. <CChevalier@gibbonslaw.com>; Gaddis, Christine A. <cgaddis@gibbonslaw.com>; Caracappa, Michael V. <MCaracappa@gibbonslaw.com>
Subject: Catalyst v. Hetero - Expert Depositions

****EXTERNAL SENDER****

Counsel,

Plaintiffs' experts are available for deposition at Sterne Kessler's office (1101 K Street NW, 10th Floor, Washington, D.C. 20005) on the following dates:

- Dr. Blair: Friday, May 16
- Dr. Winkler: Thursday, May 22
- Dr. Wymer: Tuesday, June 3
- Dr. McQueen: Friday, June 6

Please confirm acceptance of these dates as soon as feasible.

Best,
Davin



Davin Guinn

Associate

Sterne, Kessler, Goldstein & Fox P.L.L.C.

1101 K Street NW, 10th Floor, Washington, DC 20005

Email: dguinn@sternekessler.com

Direct: 202.772.8530

IP Assistant: Renée Moore

Direct: 202.772.8820 Main: 202.371.2600

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